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In re the Application of : CHARI

Application No. 09/671,995

Group Art Unit: 1624

Filed: September 29, 2000

Examiner: M. Tran

For: Compositions and Methods for Treating Cancer Using  
immunoconjugates and Chemotherapeutic Agents

Attorney Docket No: 104322.198US1

Assistant Commissioner of Patents  
Washington, DC 20231

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7-10/01  
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Provisional Response to Restriction Requirement and  
Request for Reconsideration of Restriction Requirement under 37 CFR § 1.143

This Response is submitted in reply to the restriction requirement dated May 30, 2001, for which a response is due on or before June 30, 2001.

Applicant respectfully requests reconsideration of the restriction requirement dated May 30, 2001, for the reasons herein.

**I. The First Restriction Requirement of March 15, 2001**

On March 15, 2001, the Examiner issued the following restriction requirement:

Group I      Claims 1-32   Drawn to methods of treating cancer.

Group II     Claims 33-39   Drawn to methods of inhibiting cell growth.

Group III    Claims 40-41   Drawn to compositions and kits.

Group IV    Claims 42-43   Drawn to methods for treating autoimmune diseases.

The claims in Group I, claims 1-32, included methods for treating cancer by administering a chemotherapeutic agent and an immunoconjugate comprising a cell binding agent and an anti-mitotic agent (claim 1). The cell binding agent in claim 1 could be an antibody (claims 10-15). The anti-mitotic agent in claim 1 could be a maytansinoid (claims 6-7); a *Vinca* alkaloid (claims 8-9); a dolastatin (claims 8-9) or a cryptophycin (claims 8-9). The chemotherapeutic agent in claim 1 could be a taxane (claims 16-20), a platinum compound (claims 21-24), a camptothecin compound (claims 25-26), an inhibitor of DNA topoisomerase I compound (claim 27).

The Examiner did not restrict claim 1 to the particular chemotherapeutic agents, cell binding agents, and anti-mitotic agents presented in claims 1-32.

In response to the restriction requirement, Applicant elected Group III and added composition and kit claims that corresponded to pending method claims 2-32, *which were not further restricted by the Examiner* in the First Restriction Requirement dated March 15, 2001.

## **II. The Second Restriction Requirement of May 30, 2001**

The Examiner now asserts that added claims 44-89 must be further restricted as follows:

- Group I,      Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of a taxane.
- Group II,      Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of a platinum compound.
- Group III,      Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of a camptothecin compound.
- Group IV,      Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of an inhibitor of DNA topoisomerase I compound.
- Group V,      Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of a taxane.
- Group VI,      Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of a platinum compound.
- Group VII,      Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of a camptothecin compound.
- Group VIII,      Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of an inhibitor of DNA topoisomerase I compound.

## **III. The Second Restriction Requirement Is Not Proper**

The Second Restriction Requirement and the Examiner's position asserting the necessity thereof is contrary to the Examiner's action in the First Restriction Requirement of March 15, 2001, in which *the same claims, presented as method claims, were not restricted*. In view thereof, Applicant respectfully submits that the Second Restriction Requirement is improper, and that claims 40-41 and 44-89 should be considered together, just like claims 1-32 were considered together in the First Restriction Requirement.

Moreover, the Second Restriction Requirement completely ignores claim 46 where the anti-mitotic agent is a dolastatin or a cryptophycin. Applicant respectfully submits that such a restriction requirement is improper. In support thereof, Applicant refers to the August 22, 2000, minutes from the Chemical Pharmaceutical Customer Partnership Meeting, which states:

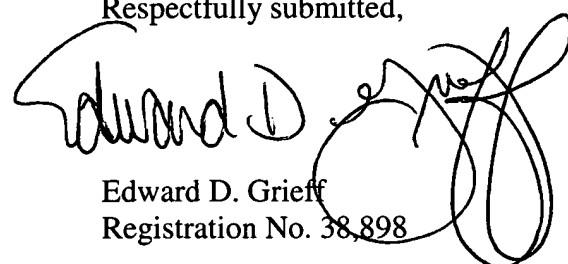
Richard Schwartz presented on restriction practice. He stated that to make restriction practice work is very simple. First you divide by one proper election species or two by group. *Conditions on restricting a claim is to sum up the parts which must equal the whole. A written descriptive support must exist for each part.* Richard Schwartz also provided information on the election of species in Markush-Type generic claims and claims containing no Markush groups.

Applicant respectfully submits that the Patent Office's procedure for restriction practice has **not** been followed in the Second Restriction Requirement, and is improper in view of the First Restriction Requirement.

#### **IV. Response to Second Restriction Requirement**

In response to the Second Restriction Requirement, Applicant elects Group I, with traverse. Applicant respectfully requests reconsideration of the restriction requirement and consideration of all of the pending claims

Respectfully submitted,



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